K014028

IV. 510(K) SUMMARY: CARESIDE *APTT* TIME SAFETY AND EFFECTIVENESS

I. Applicant Information

A.	Applicant Name	**CARESIDE, Inc.**
B.	Applicant/Manufacturer Address	6100 Bristol Parkway Culver City, CA 90230
C.	Telephone Number	310-338-6767
D.	Contact Person	Kenneth B. Asarch, Pharm.D., Ph.D.
E.	FAX Number	310-670-6986
F.	e-Mail Address	kasarch@careside.com
G.	Date 510(k) Summary prepared	December 4, 2001

II. Device Information

A.	Device Name (Trade)	**CARESIDE *APTT***
B.	Device Name (Classification)	APTT test system
C.	Device Classification	Hematology and Pathology Panel Activated partial thromboplastin time test system Regulation Number: 21 CFR 864.7925 Regulatory Class 2 Classification Number: 81GFO
D.	Special controls and performance standards	Subject to performance standard, but none published

III. Substantial Equivalence Claim

A. General equivalency claim

The ability to monitor clotting time tests in a variety of formats is widely recognized and has gained widespread acceptance.

Activated partial thromboplastin time *in vitro* diagnostic products are already on the U.S. market, including activated partial thromboplastin time products that utilize optical clot detection and reagents based upon rabbit brain phospholipids and a silicate activator, kaolin.

B. Specific equivalency claim

This CARESIDE *APTT* test is substantially equivalent in principle, intended use, and clinical performance to the currently marketed Actin® (also known as Dade Actin, manufactured by Dade Behring) reagent for the quantitative measurement of activated partial thromboplastin time on Medical Laboratory Automation's (MLA) Hemoliance Electra 900C (henceforth refered to as Electra 900C or MLA Electra 900C).

Name of Predicate Device:	Dade Actin on the Electra 900C.
Predicate Device 510K number:	K884863 (MLA Electra 900C) K760318 (Dade Actin)
Product Code:	81GFO

IV. Device Description

CARESIDE *APTT* cartridges are used with the CARESIDE *Analyzer* to measure activated partial thromboplastin time from citrated whole blood or plasma as the applied sample. The CARESIDE *APTT* cartridge, a single use disposable *in vitro* diagnostic test cartridge, aids in specimen separation and delivers a measured volume of plasma to a cartridge cuvette to initiate the measurement of an activated partial thromboplastin time. The patented cartridge contains all reagents necessary to measure an activated partial thromboplastin time.

a. Explanation of Device Function

Each CARESIDE *APTT* cartridge consists of a cuvette with dried rabbit brain phospholipid with kaolin mounted in a plastic cartridge with a hinged lid. The user introduces the citrated whole blood or plasma specimen into the cartridge sample well, closes the lid and inserts the cartridge into the CARESIDE *Analyzer*.

Once loaded, the CARESIDE *Analyzer* scans the cartridge barcode, brings the cartridge and the contained specimen to 37°C, and spins the cartridge to move the sample from the Sample Well into the cartridge channels and chambers. As the cartridge continues to spin, the blood cells are separated from the plasma and the cells accumulate in the Separation Well.

The APTT test is a two-step process. The first step of the APTT test involves reconstitution of the dried reagent in the cartridge cuvette by the sample and subsequent incubation. Forty microliters of citrated plasma remains in the metering passage after spinning is completed. Any excess sample flows into an Overflow Well. The metered volume of sample is dispensed into the cuvette by a plunger that displaces a flexible seal that covers the Sample Well while a second plunger seals the cartridge vent. As the flexible seal is displaced, air is pushed through the metering passage, forcing the sample out and into the cuvette. The sample reconstitutes the dried reagent in the cuvette. The sample and reagent within the cartridge is mixed and incubated for 3 minutes.

In the second step of the APTT, 80 microliters of a 15 mM calcium chloride pouch reagent is added to initiate the coagulation reactions. To accomplish the addition, a plunger breaks a foil pouch housed within the test cartridge and pushes the calcium chloride reagent into the cuvette. The calcium chloride is mixed with the sample and a phospholipid/activator. The cuvette is then positioned over an LED and the coagulation event is optically monitored. An onboard timer automatically measures the coagulation time.

b. Test Cartridge Architecture

Dried APTT Reagent $\xrightarrow{Sample}$ **APTT Reagent/Plasma**

Contact Activated Plasma $\xrightarrow{Calcium}$ **Stable Clot**

c. Test Summary

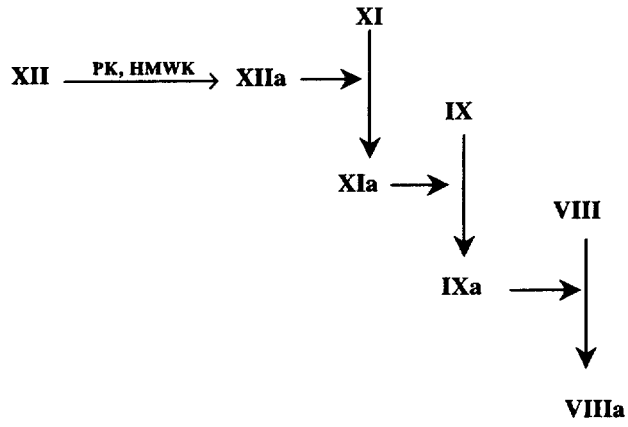
Phospholipids, a contact activator, and calcium are required to initiate clotting in an APTT test. The use of a contact activator, kaolin, which standardizes the activation of factor XII is an advancement (introduced over 30 years ago) over the original partial thromboplastin time test (PTT).

Under these conditions, the time required for the formation of a fibrin clot provides information regarding the presence and activity of coagulation factors. An activated partial thromboplastin time test is recommended to be sensitive to coagulation factor abnormalities and to factor inhibitors affecting coagulation factors VIII, IX, X, XI, XII, prekallikrein, and kininogen. CARESIDE *APTT* is sensitive to deficiencies in these factors.

Activated partial thromboplastin time tests are used as a screening test for the intrinsic and common coagulation pathways. APTT is commonly used to monitor heparin anticoagulant therapy.

Intrinsic Coagulation Pathway

[Abbreviations: Roman numerals refer to factors, subscript "a" refers to activated form, PK refers to prekallekrein, and HMWK refers to kininogen (high molecular weight kininogen)]



$$X \xrightarrow[Ca^{++}]{VIIIa} Xa$$

$$\text{Prothrombin} \xrightarrow{Xa,\ Va} \text{Thrombin}$$

$$\text{Fibrinogen} \xrightarrow{\text{Thrombin}} \text{Fibrin} \rightarrow \text{Cross linked Fibrin}$$

V. Intended Use

A. Intended Use

The CARESIDE *APTT* cartridge is intended for *in vitro* diagnostic use in conjunction with CARESIDE *Analyzer* to quantitatively measure activated partial thromboplastin time in citrated whole blood or citrated plasma.

B. Indications for Use

For *in vitro* diagnostic use with the CARESIDE *Analyzer* to measure activated partial thromboplastin time from citrated whole blood or citrated plasma as an aid in the diagnosis of patients with clotting disorders and to monitor patients receiving heparin anticoagulation therapy.

VI. Technological Characteristics

A. Similarities

	CARESIDE *APTT*	**Actin on Electra 900C**
Intended Use	For *in vitro* diagnostic use to aid in the diagnosis of patients with clotting disorders and to monitor patients receiving anticoagulation therapy.	For *in vitro* diagnostic use to determine the activated partial thromboplastin time and other coagulation tests requiring an activated partial thromboplastin reagent.
Measurement type	Quantitative	Same
Method Principle	Optical clot detection based upon rabbit brain phospholipid reagent with kaolin activator	Optical clot detection based upon rabbit brain phospholipid reagent
Specimen dilution	Not required	Same
Materials	Rabbit brain phospholipid with kaolin + calcium chloride	Rabbit brain Cephaline (phospholipid) in ellagic acid + calcium chloride
Detection Principle	Photometric detection of "knee" of transmission-time trace; 570 nM	Same; 550 nM
Test time	Approx. 12 minutes: includes warm-up (on-board), and incubation, and 3 minutes clot monitoring time.	Warm-up, 3 minute incubation, plus clot monitoring time.
Sample Type	Citrated whole blood or Citrated plasma	Citrated plasma
Specimen volume	40 microliter test volume (300±50 microliter applied whole blood or plasma)	100 microliter volume (plasma)
Quality Control	External, multi-level controls	Same
Reporting Units	Sec	Same
Reaction Temp.	37°C	Same

B. Differences

	CARESIDE *APTT*	**Actin on Electra 900C**
Direct blood specimen	Yes, whole blood	No, requires separation of whole blood prior to sample application
Reportable range	20 to 140 sec	14 to 106 sec
Accurate pipetting	Not required	Required
Reagent pre-warming	Not required	Required

C. Comparative Performance Characteristics

	CARESIDE *APTT*	**Actin on Electra 900C**
Reportable range	20 to 140 sec	14 to 106 sec
Accuracy via Method comparison	CARESIDE = 0.96 (Actin on Electra 900C) + 3.16 sec, r = 0.94	
Precision	Total CV, 29sec, 4.1%	Total CV, 25sec, less than 5%
Interference	No significant interference observed at tested concentration of interferent: Bilirubin 10 mg/dL Hemoglobin 250 mg/dL Triglyceride 390 mg/dL	Not provided.

D. Conclusion

The nonclinical and clinical data provided demonstrate that the CARESIDE *APTT* product is as safe, effective, and performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 0 8 2002

Kenneth B. Asarch, Pharm.D., Ph.D.
VP Quality Systems and Regulatory Affairs
CARESIDE, Inc.
6100 Bristol Parkway
Culver City, CA 90230

Re: k014028
Trade/Device Name: CARESIDE *APTT*
Regulation Number: 21 CFR 864.7925
Regulation Name: Partial thromboplastin time tests
Regulatory Class: Class II
Product Code: GFO
Dated: December 4, 2001
Received: December 6, 2001

Dear Dr. Asarch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VI. INDICATIONS FOR USE

510(k) Number: K014028

Device Name: CARESIDE *APTT*

Indications for use: For *in vitro* diagnostic use with the CARESIDE *Analyzer* to measure activated partial thromboplastin time from citrated whole blood or citrated plasma as an aid in the diagnosis of patients with clotting disorders and to monitor patients receiving heparin anticoagulation therapy.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014028

✓ Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___
(Optional Format 1-2-96)